IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

METHODS AND DEVICES FOR REDUCING STRESS CONCENTRATION WHEN SUPPORTING A BODY

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TITLE OF INVENTION

Methods and Devices for Reducing Stress Concentration when Supporting a Body

CROSS REFERENCE TO RELATED APPLICATIONS

Not applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable

REFERENCE TO A MICROFICHE APPENDIX

Not applicable

BACKGROUND

A person who is elderly or has some enervation and is confined to bed for an extended period, will have a propensity to develop tissue trauma sores (ischemic ulcers, decubitus ulcers or bedsores). Typically these sores appear over bony prominences where forces arising from the weight of the body are concentrated and the lack of movement leads to tissue destruction. (Those with normal sensation and mobility become "uncomfortable" and move to a different position while those under anesthetics can't move) To avoid such sores, some form of tissue pressure/shear interface should be provided to reduce these forces to a value that the tissue can tolerate. These tissue trauma forces may be

adjusted in a number of ways; by "putting the load where the body can tolerate it", by attempting to control interface forces across the patient body support surface, or by moving the patient periodically before tissue reaches an irreversible "death" situation.

DESCRIPTION OF PRIOR ART

In recent years, inventors have approached this problem of tissue breakdown prevention using two basic approaches for body support, fluidic substance or polymeric foam. Each of these methods encompasses many variations that have met with differing degrees of success. In most instances cross-contamination or dust mite prevention has not been considered as part of a performance requirement until after-the-fact

1. Fluidic support

Water/Air. Making use of a shaped structure and air bladders was proposed by Weinstein et al in US Patent 3,456,270 wherein water was the supporting medium and a lifting inflatable bladder interface was used for raising patient for transfer etc.

Whitney in US Patent 3,802,004 changed a patient immersion depth through unique bladder arrangements inflated by air, without changing medium volume.

Hagopian in US Patents 5,072,468 and 5,068,935 describes a special bed frame for ease of manufacture and the use of water as the base medium with an air bladder on its upper surface to lower or raise the patient, as in

Reswick (later), with the added ability to provide an inflated wedge for postural trunk control of the patient. These approaches also were an attempt to reduce "hammocking" over bony prominences that tends to negate the efficacy of the support medium. It should be noted that the water bed of today is comprised of water, a supporting envelope to "hammock" a person so that they do not sink into the bed and appropriate baffling or channeling for stability of the water.

Air. There are a number of ways in which air has been compressed, blown or applied to support a patient. Hart in 1926 in U.S. Patent # 1,772,310, described a technique of alternating the fluidic support points on the body by controlling the time each support point was to be activated, while limiting interface pressure to an acceptable value. Hart also introduced a method of patient turning in this same patent.

Whitney, in US Patent 3,148,391 used a modified method of support that was compact and introduced temperature control of interface as well as the alternating method of support. Ford in US Patent 4,711,275 opted to inflate and deflate arrays of air cells through independent air compressors to create an alternating pressure support system. Krouskop in US Patent 4,989,283 opted to control height of the supporting bladders in his approach to body support by measuring any changes in cell configuration through a microprocessor using its input from internal bladder sensors.

to control appropriate valving to pressure sources or exhausts to maintain each bladder at some referenced height. Others used lateral support tube shaping (Talley of the UK) while others included an air loss to circumvent needle puncturing problems (3M) with appropriate control mechanisms.

Air, as a fluidic support has been proposed in many forms for various purposes of body positioning. A surgical table is the subject of Canadian Patent 1035000 by Carrier where individual bladders of air are positioned to keep the bony prominences clear of the table, while providing a fairly stable support as each bladder is independently inflated to a desired pressure. All are then covered by a forgiving cover.

Air cushion machines are quite effective in supporting a large unforgiving body against a homogenous and somewhat stiff undersurface; however, their use as a patient support medium is impractical. Then again, if enclosed in a container of soft tough and highly flexible material, air is much more suitable for patient support if designed correctly to reduce hammocking.

Consequently, by using air in tubular or oval containers and arranging appropriately within the bed frame, a mattress of air tubes is a reasonable approach, depending on cross sectional area of bladders and their positioning. Shaping these air tubes and putting holes in them to circumvent accidental needle punctures and with a pump sufficiently large to keep ahead of the leak rate, had its merits.

Although Armstrong, US Patent 2,998,817, first developed an inflatable massaging and "cooling" system, as time passed, materials were developed that had built in leak rates suitable for beds and thus the current Low-Air Loss mattress approach evolved using so-called vapor-permeable materials. Such materials may consist of 80 denier nylon, or thereabouts, backed with a material of choice such as a film of urethane or vinyl.

Hess, US Patent 4,638,519, demonstrated use of shaped bladders using such materials with appropriate individual bladder control and methods of bladder attachments with air supplies while Goode, US Patent 4,797,962, used the process of controlling these air bladders in groups as a means of modifying support pressure under portions of the body as others have done in the aforementioned. (Some of these approaches have been prone to collapse when the patient is in the sitting position in the bed, consequently exposing the coccyx and ischial tuberosities [sit bones] to excess pressure and shear due to increased bladder loading by the vertical component of the trunk.)

Some have attempted to reach suitable body support through the use of foam on top of slats placed on top of air cylinders as outlined by Wilkinson, in US Patent 5,070,560.

<u>High Density Fluid</u>. Reswick, in US Patent 3,803,647, used a mixture of Barium sulfate ore and water (or other fluids) as a medium of support with a loose fitting lifting interface sheet as the top member of the unit. This sheet was

inflated and allowed access to the patient at a suitable working height for the attendant personnel. The aqueous solution of barites was used as its specific gravity could be much greater than "1" and thus support a body without immersion problems of water only. This specific gravity, greater than "1", allowed the patient to lay in the solution and be supported up the body sides to an optimum immersion point. If the specific gravity is too high, excess pressures can be exhibited as area of support is drastically reduced. Keeping the mixture sufficiently fluidic presented a maintenance problem that led to patent disuse.

This patent also addressed shaping of the container to reduce the contained mixture volume and of a tubular top bladder as a stiffening method of the upper surface of contained fluid for easier patient transfer or performing dressing changes.

Thompson, US Patent # 4,357,722, demonstrates a flexible open mesh approach in a special bed frame to support the patient interfacing medium to change tension of support under various portions of the body.

Hargest et al, US Patents 3,428,973 and 3,866,606, used fluidized beads to create a specific gravity greater than "1". These beads were micro-balloons approximating 100 microns in diameter and were "fluidized" by an air plenum chamber placed at the base of the beads separated by appropriate filtering and restrained to remain adjacent to the patient by another optional filter. Fluidization depends on the pressure drop

across the supporting beads and that of the filtering system. Excess drop reduces fluidization, increases heat loss and can create ballooning of upper cover. It is thus necessary to adjust pump flow to match patient needs and size.

Lacoste, US Patent 4,481,686 controls bacteria through bead selection.

Goodwin addresses support of beads in his US Patents 4,564,965, 4,672,699 and 4,776,050 with sequential diffusion of beads in 4,637,083.

Viard in US Patent 5,402,542 demonstrates use of a programmable EPROM and heat exchanger to control bead system component temperatures.

River sand has also been used in place of beads and periodically "fluidized" with marginal success.

Yet another approach that may be considered somewhat fluidic is the use of gel and air wherein a semi fluid gel is used in place of the fluidic bead systems in much thinner beds than the units discussed above. Due to the nature of the gel, however, its accommodation of high forces is somewhat limited.

2. Use of polymeric foam such as polyurethane

Flat Stock. Polyurethane is formed through the mixing of different polymers under controlled conditions. Some manufacturers provide the fabricator with huge blocks of foam which are then cut into required sizes and sold to various fabricators of furniture, mattresses and so on. Some of this stock is sold as is or as a finished item when placed within

some acceptable cover consistent with industry requirements. Some foam is rigid and some flexible.

As can be readily acknowledged, flexible foam acts somewhat like a spring. It is well known that the further a spring is compressed the stronger is the resisting force of that spring, and so it is with foam. The unfortunate part of this foam as a support media is that our bodies are not flat and our hips protrude further than our waist Accordingly, when one is sidelying on foam, the hip sees more "spring-back" (foam fightback) or a higher load than our waist. This hip bone (Trochanter) is poorly vascularized and thus the tissue at its surface can be robbed of the desired blood to keep the tissue healthy. Thus the enervated person is unaware of the damage being incurred with this load, the tissue dies, and the result is a "sore" where the skin integrity is forever damaged without surgical intervention. Other parts of our bodies such as the heels, malleolus (ankles), iliac crest (pelvis), coccyx (tailbone), ischial tuberosities (sit bones), scapula (shoulder blades), occiput (back of head), elbows and ears are areas that are also poorly vascularized and prone to breakdown with small loading of tissue in these areas.

Those with normal sensation and mobility feel this excess tissue load as a discomfort and move away, thereby restoring circulation in the region. It has been clinically noted that a sleeping person will normally move more than twenty times during an eight hour period on a "so called", standard mattress.

Thus flat stock foam, using current technology, is not very desirable for patients at-risk of tissue breakdown or for their comfort. Some materials tend to give way with applied load as in the case of materials used for the Apollo astronaut couches, however, this material known as "visco-elastic foam, is expensive, is temperature sensitive, heavy, flaky, tends to tear readily, and has not been generally used by the bedding industry in the past.

Flexible polyurethane foam has been the material of choice most recently. These materials are available in many densities and Indention Force Deflections (IFD). Densities may range from the soft 1.1 pounds /cubic foot up to about 7 pounds /cubic foot and an IFD range of about 14 to 180 is commonly used for bed support purposes. These foams are generally manufactured as a polyether, polyester, high resiliency or other, foam, with all exhibiting different characteristics. The polyether materials are generally found in furniture while the polyester is used in packaging requiring fire resistance while high resiliency may be found where continual cycling is encountered. Other foams also include rubber and other compounding which have not found great favor in the bedding/cushioning industry.

Although combinations of many of these foams is common knowledge in the industry, polyether material is less expensive and it may be found in products where replacement is no problem or where material is not used extensively. Its

durability under continual loading has generally been less than desirable.

Cut or Shaped Foam Stock. Reducing forces encountered in flat stock of polyurethane was obtained through reduction of a foam support in the bony areas by cutting the foam in a special pattern as proposed by Rogers (the inventor herein) in US Patents 3,885,257, 3,866,252 and 4,042,987. Others also cut foam as disclosed in US Patents 3,828,378 by Flam, 4,901,387, by Luke and later 5,025,519 and 5,252,278 by Span. Kraft in US Patent 4,679,266 simulated foam support by zones of inner (mattress) springs with varying strengths.

Murphy in US Patent 4,628,557 and Rogers (inventor herein) in 4,042,987 and 4,903,359 could make a selection of foam removal under affected areas of the patient, and in Rogers's case, overloaded adjacent support members rolled automatically into the vacancy to spread load gradually to adjacent areas. Bony areas of the body can be free of all force in foam products through use of material cutouts in mattresses, mattress replacements, body conforming supports, or cushions, but shearing forces at the demarcation edge of support and no support are a harbinger of tissue death unless that demarcation is gradual and can be overcome by the body's internal blood pressure without creating total occlusion of the blood supply. It is then of paramount concern that proper shaping of the edges of regions where foam is removed is built into any design of a support surface so that loading is transferred gradually to adjacent support areas of the body

more amenable to the applied forces (putting the load where the body can tolerate it). Some methods to do this are disclosed in US Patents 5,127,119 and 5,048,137 by Rogers (inventor herein). Foam is cut away from bony areas and edge or shear effects are accommodated by cutting foam around the removed foam area to create supporting foam forces "normal" to the body and give a gradual buildup of load over a reasonable area where blood flow is not compromised. One patent discloses technique of load spreading through shaping of the cutout conically or approaching a bell shape.

Convoluted foam, initially used in anechoic chambers, is formed from flat stock put through a convoluting machine, and has been used as a mattress or pad where patient is supported by a number of peaks and valleys, such as described by Schulper, in US Patent 3,197,357. This machine can produce two products 4" thick from one five inch piece of foam. Obviously material is spread equally between the two halves in such a manner as to create a peak of four inches with valleys to offset the adjacent peaks, a type of "mirror" image.

Peak sizes were varied as well as depth of valleys in an attempt to equalize forces without complete relief of affected areas. In some instances manufacturers cut the peaks off some of these convoluted pads in an attempt to control support load distribution. Most of this type material was fabricated from inexpensive foam and has been banned from use in many medical facilities across the USA because of its inability to eliminate damaging forces on body tissue when the user had

expected more protection than the material could provide without extensive forming, cutting or modified as proposed in the subject patent.

SUMMARY OF THE PRIOR ART

From the foregoing, it is clear that many different approaches have been used in an attempt to reduce discomfort and injury in a bedridden patient. Such discomfort and possible injury is a direct result of the stress concentration created by the non-uniform shape of the human body. An ideal supporting structure would distribute the forces due to the body weight in a way to minimize or eliminate any localized concentrations of stress, particularly shear, such as would occur at a discontinuity in the underlying material.

However, this does not mean that a uniform distribution of stress is the most desirable result. Where bony structure in the body is near the surface and not protected by a reasonable thickness of soft tissue, an effort should be made to greatly reduce or even to eliminate the stress in that region, compensating by slightly higher forces elsewhere, where the body can tolerate it. Total elimination of stress locally is particularly important to promote healing where a bedsore or injury already exists so that the affected site can be readily supplied with a healthy flow of blood. This same thinking is also appropriate for all sites of the body where blood flow may be compromised by an inappropriate body support medium.

The prior art has not as a rule directly addressed this goal. Although it has been generally recognized that a support structure for the human body needs to provide different stress patterns in different areas, most schemes do not fully achieve it. In fact, some have discontinuities in material and make no apparent attempt to minimize shear stress at those points.

BRIEF SUMMARY OF THE INVENTION

This invention relates to the support of a person in the prone, supine, sidelying, semi reclined or sitting position without the usual stress concentrations which may lead to tissue trauma, decubitus ulcers or bed sores. It is an object of the present invention to provide support for a human body in a manner so that the forces of support have fewer concentration points which are likely to occur at or near bony prominences, nerves, or tendons, and which, if not accommodated, can lead to serious complications such as bed sores, nerve damage, or strained tendons.

This invention addresses the stress distribution problem by combining several techniques. First, using a basic foam inner material, or other that gives a similar performance, the invention provides regions where material has been cut in some selected manner, cut away, omitted, or formed to reduce the magnitude and abruptness of any stress concentrations when supporting a body. This technique is then combined with the process of applying a membrane over the insert material to

smooth out the localized variation in stress and concomitantly, if the membrane is able to control the amount of air or fluid surrounding the space between the bladder and interstices of the foam, the fluid pressure may be varied to change the characteristics of the foam itself. This can be characterized by reviewing US patents 5,127,119 and 5,048,137 by Rogers and observing that if these patented products were loaded by a body, the foam will "fold" over "normally" to the tissue of the body to reduce the shearing occurring at the tissue. However, if a bladder were to also be placed between the body and the supporting foam discussed, the bladder, with air control ability, can hold the foam in its desired place without the normally concurrent fightback of the foam and thus the "shear" or pressure known to damage the tissue, nerves, and tendons. The body is virtually floated by a high specific gravity through a combination of foam, bladder and fluid pressure. But, the foam or supporting medium must be previously pre-shaped for this system to work as designed.

It is this combination of techniques that accomplishes, in a superior way, the desired goal of comfort and safety of the patient. "Comfort" has been shown to be directly related to forces exerted on the body by Rogers in the "Hospital Materiel Management Quarterly" article, "Body Support Testing and Rating" dated August 1992.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

Figure 1 is an embodiment wherein a foam mattress, containing one or more regions where foam has been cut away, is inserted into a closely fitting bladder in which the pressure of a fluid can be controllably varied.

Figure 2 depicts the deformation of a foam material around a cylindrical cut-out in the material when an irregular object is placed thereon.

Figure 3 shows how the material deforms when an inverted conical hole is in the support material.

Figure 4 shows how the material will deform if the cut-out is tapered away from the hole progressively from top to bottom.

Figure 5 shows a detail of the deformation around a cut-out placed within a bladder.

Figure 6 is a view of an insertable foam pad with undercut edges.

Figure 7 depicts an insert containing modules of different types of foam in different areas with undercutting at the joint.

Figure 8 shows a modular device with individually pressurized sections.

Figure 9 shows a convoluted foam material inserted into a bladder.

Figure 10 shows a convoluted pad inserted with smooth side up, containing a cut-out for localized pressure relief.

DETAILED DESCRIPTION OF THE INVENTION

The basic features of the invention can be seen in figure 1. A foam pad 1 of any size or shape, containing one or more cutouts 2, is inserted into a closely fitting airtight bladder 3. A valve 4, is affixed to an opening 5, and an optional pumping means 6, for pressurizing or evacuating the bladder may be attached. It should be noted that the shape of the pad in figure 1 is for demonstration only and that the pad may also be in the shape of a torus, a circle, or a square for example, with a rectangular, or other-shaped center portion removed, or for that matter, any suitable body supporting shape.

As demonstrated by Rogers(inventor herein), U.S.Patent #5,048,137, the deformation of a foam mattress around an opening through the foam in the form of a truncated upright cone(small radius at top)or bell-shaped, is such that the material around the edges of the opening tends to "roll" into the cavity when a load is placed upon the portion of the mattress containing the cut-out. The result is that instead of an abrupt change in force distribution at the edge of the cut-out, the distribution changes more gradually at the approach to the opening. This desirable condition comes about because the shape of the cavity is such that there is gradually less and less material as the edge of the opening is approached, hence the spring constant or fight-back is reduced near the cut-out in a manner suitable for gradual force

reduction commensurate with blood pressure supply to the supported site.

However, the gradual diminishing of the forces on the body as the cut-out is approached only occurs where the material slopes back away from the opening into the foam. If the sides of the opening are vertical, whether a cylindrical, elliptical, or other shape, the body will see a higher stress concentration near the opening. This effect can be seen in figure 2. Since the force on the body is proportional to the amount of compression of the underlying material, when a body of irregular shape as shown, is supported over the opening, the forces will increase near the cut-out, and drop sharply within the opening.

On the other hand, as in figure 3, where the top of the opening is larger in cross section than below, the body will see a stress concentration near the edge of the opening, and also at the point where the body loses contact with the underlying material and is unsupported across the opening. But where the opening is undercut as in figure 4, whether the opening is in the form of an inverted cone or of some horizontal cross section other than circular, as the opening is approached there is less material under the body and the forces upon the body will be reduced gradually because the material can bend or "roll" into the opening as shown with a reduced "spring constant" and concomitant force on the supported body.

Thus, figures 2,3,and 4 demonstrate how the shape of the cut-out plays a significant role in controlling stress concentrations in supporting a body.

Now, when the foam or other material is placed inside a bladder wherein the fluid pressure may be varied, two additional effects are observed. First the membrane of the bladder extends over the opening adds support to the supported body in the form of a "hammocking" effect. The amount of hammocking support will be determined by bladder composition and adds considerably to the smoothing effect, further reducing any abrupt changes of pressure on the body.

Another factor arises from the ability to vary the pressure of the fluid inside the bladder. Within the cells of the foam the variation of pressure changes the spring constant of the foam. At the same time, in the cut-out section, the pressure of the fluid directly determines the local force distribution on the supported body. This is shown in more detail in Figure 5 which is a cross section of an undercut cut-out encased in a bladder showing the resulting deformation of the foam.

Thus, the invention disclosed herein provides for simultaneously varying both the shape of the supporting material and its resiliency. These variations are accomplished by selectively cutting, removing, omitting or shaping material and by varying the resiliency of the material with fluid pressure in the cells of the material.

In one embodiment, the invention is a foam pad shaped as desired for a mattress, pillow, body support device or cushion, which contains one or more cut-outs in preselected locations. These cut-outs will preferably have outwardly sloping sides, being smaller at the top than at the bottom. It is obvious that the amount of force gradation on the supporting body is directly related not only to the type of support material but also the slope and shape of the cutout, the bladder material, and the amount of contained fluid. Therefore, it is possible to tailor the support device to the needs of the body resting thereon.

If the edge of the support structure impinges on any portion of the body, such as the heels or the back of the knees when seated, then in order to avoid stress concentration, that edge should be sloping inward from top to bottom as in figure 6. Figure 6 shows the same type of roll-over effect as earlier shown in the cut-outs. The same principle also applies to the inner surfaces of a ring or a so-called doughnut. Otherwise a tourniquet effect will reduce the blood supply in the center and create a blood flow limiting situation and the possibility of tissue death within the ring.

The foam insert is placed in a close-fitting bladder or membrane containing a passageway for air or other fluid to enter or leave. A valve or other means for controlling the internal pressure may be fitted to the bladder as was shown in figure 1. This fitting may be connected to a pressure or

vacuum pump or simply left open initially and closed when the body is in position upon the mattress, pillow, support module, or cushion. In this latter case the foam fight-back has been reduced over sloping edges making the body support surface free of unwanted shear at the edges. Without the outer membrane and with the surrounding air pressure normal such shear is likely to be encountered.

Alternatively, it may be desirable to simply hermetically seal the bladder either by conventional sealing means or by a Ziploc® type closure after establishing the desired internal pressure. On the other hand one might use a semi-permeable membrane or a controllable orifice so that the weight of the body would force the air out slowly, allowing the pad to assume a shape conforming to the body. Of course cut-outs may be placed in appropriate locations to further enhance the patient's comfort and tissue health, however, if cross-contamination or dust mite restriction is part of the patient physical support consideration, appropriate filtering or support personnel regimen must be considered in the overall performance specification of the patient physical support system.

Another method of varying the resiliency of the support is to cut a number of slits in the material as was shown by Flam, U.S.Patent 3,828,378. The placement of these slits will result in varying compressibility or resiliency. By combining this technique with the pressure variation in the bladder and optional cut-outs, a much wider range of controllable

properties can be obtained. The foam, where slit will act like a collection of individual springs, much as in an innerspring mattress. It will also be possible to vary the spring effect in different areas of the mattress and then provide the bedridden person with even greater degree of comfort by changing the pressure in the mattress and/or adding shaped cut-outs.

Another means of providing variable force distribution is to use different types of foam in different areas as shown in figure 7. This would not be limited to any particular shape of the foam. For example, one could fill in one or more of the cut-outs with a softer foam plug to get even more variation in the local resiliency. Lateral strips of foam may be used and the different effects of the pressure variation in the different foams would allow a seemingly endless variety, especially if combined by the ability to vary fight-back of the supporting material by varying pressure. Cross-contamination between patients can be readily controlled as can dust mite invasion into the inner core of the unit.

A further refinement on using different foams is shown in Figure 8. In this embodiment, each section is encased in an individual bladder wherein the pressure can be maintained independently of the others. It should be noted that the principles of undercutting have been carried over from the earlier embodiments, as shown in figure 8, in order to minimize stress peaks arising from discontinuities at the joining of different foams. Where there are joints between

two types of foam, whether or not they are in independent bladders of the type shown in figure 8, the firmer material should extend over the softer one as shown in figures 7 and 8. The outer cover itself may be sloped to match the material within and assure that gradation support transfer is acceptable to tissue restraints.

Finally, figures 9 and 10 show two different techniques for using a convoluted foam material within the bladder. In figure 9 the material is inserted with the convolutions upward. In this configuration, the use of cut-outs is of less obvious value, although they would still provide some pressure relief in the areas where no material is left. Figure 10 shows the use of the convoluted material in an inverted position, where the cut-outs would be of more value in reducing pressure concentrations.

The numerous embodiments covered herein are by no means exhaustive. Some variation suggested by the foregoing techniques will no doubt occur to those skilled in the art, and the application of the above principles would follow directly.